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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : B65B 55/02, A61L 2/08 — A1

(11) International Publication Number: WO 94/14657

(43) International Publication Date: 7 July 1994 (07.07.94)

(21) International Application Number: PCT/FI93/00554

(22) International Filing Date: 22 December 1993 (22.12.93)

(30) Priority Data:
925878 23 December 1992 (23.12.92) FI

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(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: A METHOD FOR PACKAGING A PRODUCT FOR STERILIZATION AND A STERILIZED PACKAGE MANUFACTURED BY THE METHOD

(57) Abstract

The invention relates to a method for packaging a product for sterilization effected by irradiation and a sterilized package, wherein the product (1) is enclosed in a substantially gas impermeable package (2). The invention is characterized in that the product (1) is placed in the package (2), the package is deaerated and filled with a protective gas, whereafter the package is sealed for sterilization by irradiation.

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A method for packaging a product for sterilization and a sterilized package manufactured by the method

The invention relates to a method for packaging a product for sterilization effected by irradiation, wherein the product is enclosed in a substantially gas impermeable package. The invention also relates to a sterilized package manufactured by the method.

Sterile packages, such as packages for hospital equipment, are often bag-like, airproof, or air permeable but bacterium impermeable packages in which the equipment to be packaged is placed before the packages are sealed. Sterilization is effected by irradiating the package by ionizing radiation, such as gamma radiation, ultraviolet light or by some other means. The products to be packaged may be surgical textiles, surgical instruments, various tubes, syringes, cannulae, etc.

The problem with packages of this type is that when opened, they give off a strong odour. Radiation causes the oxygen within the package to be converted into ozone, which reacts with the molecular chain of the product, which is usually plastic-based, to form bad-smelling compounds, such as acetic acid and butanal. Moreover, an oxidizing environment reduces the mechanical strength of the plastic products placed in the packages. This problem has been discussed e.g. in European Patent No. 218 003. The package disclosed in this reference comprises a deoxidizer, such as activated iron oxide, for the elimination of odour. The solution requires, however, a two-layer package: a breathing inner layer and a tight outer layer, between which the deoxidizing - and thus deodorizing - agent is positioned. The disadvantages of such a package are that it is complicated and that iron oxide must be separately added thereto.

The object of the present invention is to provide such a method for sterilizing a package, and a sterilized package manufactured by the method, by means of which the product can be easily and securely packaged for sterilization, and in which the problem of odour caused by radiation in the corresponding known products has been minimized. To achieve this, the method according to the invention is characterized in that the product is placed in the package, the package is deaerated and filled with a protective gas, whereafter the package is sealed for sterilization by irradiation.

The invention has the advantages that, in addition to being odourless, the package is uncomplicated, and the different steps of manufacture can be rapidly taken. The same nozzle can be used both for removing air and for adding a protective gas. The package may be a simple plastic package, wherefore it is also inexpensive.

The other preferred embodiments of the method according to the invention and the package according to the invention are characterized by what is disclosed in the appended claims. In the following, the invention will be described in greater detail with reference to the accompanying drawings, in which

Figures 1 to 4 show the package of the invention during the different steps of manufacture,

Figures 5 to 8 show gas chromatograms of the contents of packages according to the invention and those of reference packages.

A sterile package according to the invention, containing a product (e.g. a surgical gown) to be sterilized, is manufactured by disposing a product 1 in a plastic package 2 (Figure 1), whereafter the package is deaerated e.g. by a vacuum pump (not shown) through a hose 3 (Figure 2). A protective gas, such as nitrogen

or carbon dioxide, is then added to the package 2 (Figure 3). The package is sealed and sterilized by gamma radiation (Figure 4), whereafter it is ready for use.

Practical experiments have shown that when the packaging method of the invention is used, the unpleasant odour which a package sterilized by irradiation emits when opened almost completely disappears.

Table 1 shows results based on sensory evaluation of odour (scale from 0 to 3). Sample A is a gamma sterilized package without a protective gas, sample B is a corresponding package where the protective gas is nitrogen, and sample C is a corresponding package where the protective gas is carbon dioxide. As appears from the table, most of the assessors 1-7 sense that the odour of sample A is strong (average ca 1.8), whereas the odour of samples B and C is typically hardly discernible (average ca 1). In samples B and C the oxygen

	SAMPLES		
ASSESSOR	A	B	C
1	0.75	1.25	0.5
2	2	0.5	1
3	2.25	0.25	1.75
4	2	1.5	1.5
5	1.75	1.25	0.5
6	2	1	0.5
7	1.5	1.25	1
TOTAL	12.25	7	6.75
X±SD	1.8±0.5	1.0±0.5	1.0±0.5

TABLE 1

content of the packages was below 1%, in sample A it was the normal oxygen content of air (21%). Depending e.g. on the size of the product to be sterilized, a suitable oxygen content in the package is estimated to be 0.5 to 5%.

The reason for the lack of odour or the considerable decrease in it has been studied at the University of Jyväskylä by gas chromatography and mass spectrometer measurements (Figures 5 to 8). Figure 5 shows a gas chromatogram of a package which contains air and which has not been irradiated. It can be seen that various compounds are present only in relatively low contents. Figure 6 shows the effect of irradiation when the package containing air (cf. Figure 5) is irradiated by gamma radiation. From the gas chromatogram it can be seen that, in addition to the increase in the amount of the compounds already present, two new compounds are formed in considerable amounts. These compounds are butanal and acetic acid, which are both known to have a very strong odour. Butanal and acetic acid are probably formed as a result of the reactions of ozone with the plastic materials in the package due to gamma radiation. Reactive ozone reacts with plastic polymers, causing oxidation reactions, whereby bad-smelling compounds, for example, are produced.

Figures 7 and 8 show gas chromatograms of corresponding packages which have first been deaerated in accordance with the invention and then filled with a protective gas: nitrogen (Figure 7) or carbon dioxide (Figure 8). It can be seen that the butanal and acetic acid peaks have disappeared completely or almost completely. Thus it seems that the sensed lack of odour or the considerable decrease in it is a result of the fact that in packages filled with a protective gas there are hardly any signs of two compounds with a strong odour

- butanal and acetic acid - which are present in an irradiated package containing air (Figure 6). In addition to the above-mentioned protective gases, it is also possible to use other gases for the same purpose.

On account of the insignificant formation of ozone or the lack of it during irradiation (cf. EP 218 003), which is due to the low content of oxygen, the pungent odour emitted by known packages (sample A in table I) has been eliminated in the packages manufactured according to the invention (samples B and C in table I).

It will be clear to one skilled in the art that the different embodiments of the invention are not restricted to the examples described above but can be modified within the scope of the appended claims.

Claims

1. A method for packaging a product for sterilization effected by irradiation, wherein the product (1) is enclosed in a substantially gas impermeable package (2), c h a r a c t e r i z e d in that the product (1) is placed in the package (2), the package is deaerated and filled with a protective gas, whereafter the package is sealed for sterilization by irradiation.

2. A method according to claim 1, c h a r a c t e r i z e d in that the protective gas is nitrogen.

3. A method according to claim 1, c h a r a c t e r i z e d in that the protective gas is carbon dioxide.

4. A method according to claim 1, 2 or 3, c h a r a c t e r i z e d in that the package is deaerated in such a manner that the amount of residual oxygen does not exceed 1% of the amount of gas contained in the package after the addition of the protective gas.

5. A substantially gas impermeable package (2) sterilized by irradiation, c h a r a c t e r i z e d in that it comprises a package containing a product (1), the package (2) being substantially deaerated and filled with a protective gas for sterilization by irradiation.

6. A package according to claim 4, c h a r a c t e r i z e d in that the protective gas contained in the package is nitrogen.

7. A package according to claim 4, c h a r a c t e r i z e d in that the protective gas contained in the package is carbon dioxide.

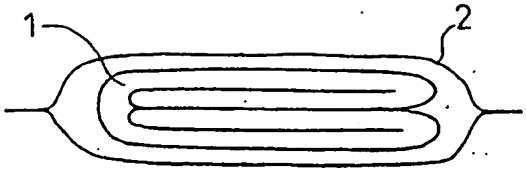


FIG. 1

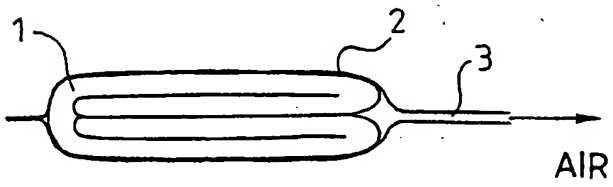


FIG. 2

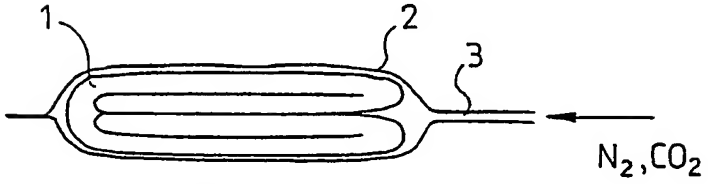


FIG. 3

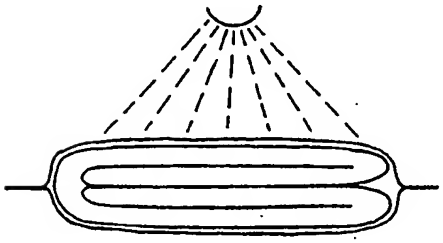
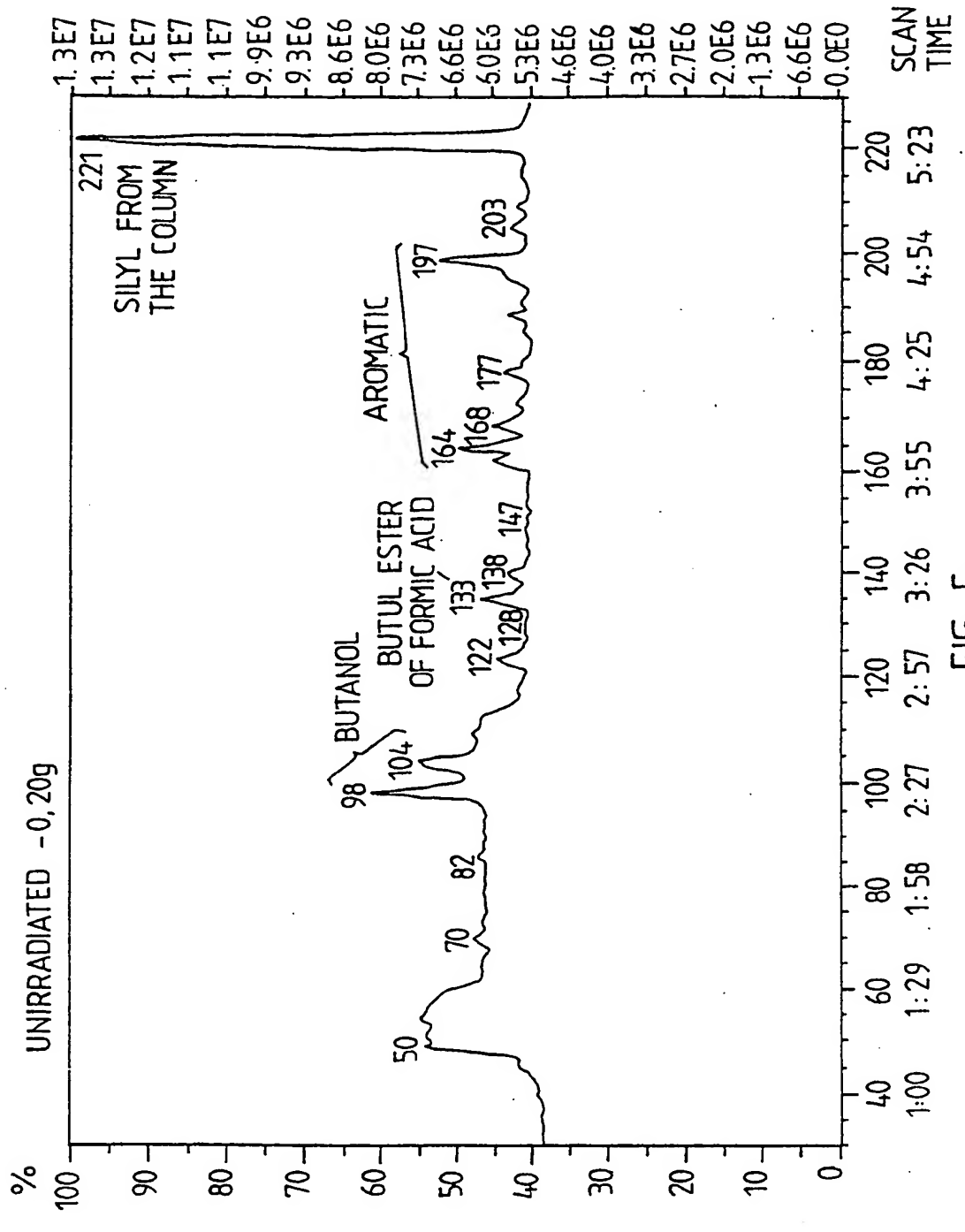


FIG. 4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%
100
90
80
70
60
50
40
30
20
10
0
1.3E7
1.3E7
1.2E7
1.1E7
1.1E7
9.9E6
9.3E6
8.6E6
8.0E6
7.3E6
6.6E6
6.0E6
5.3E6
4.6E6
4.0E6
3.3E6
2.7E6
2.0E6
1.3E6
6.6E6
0.0E0
SCAN
TIME
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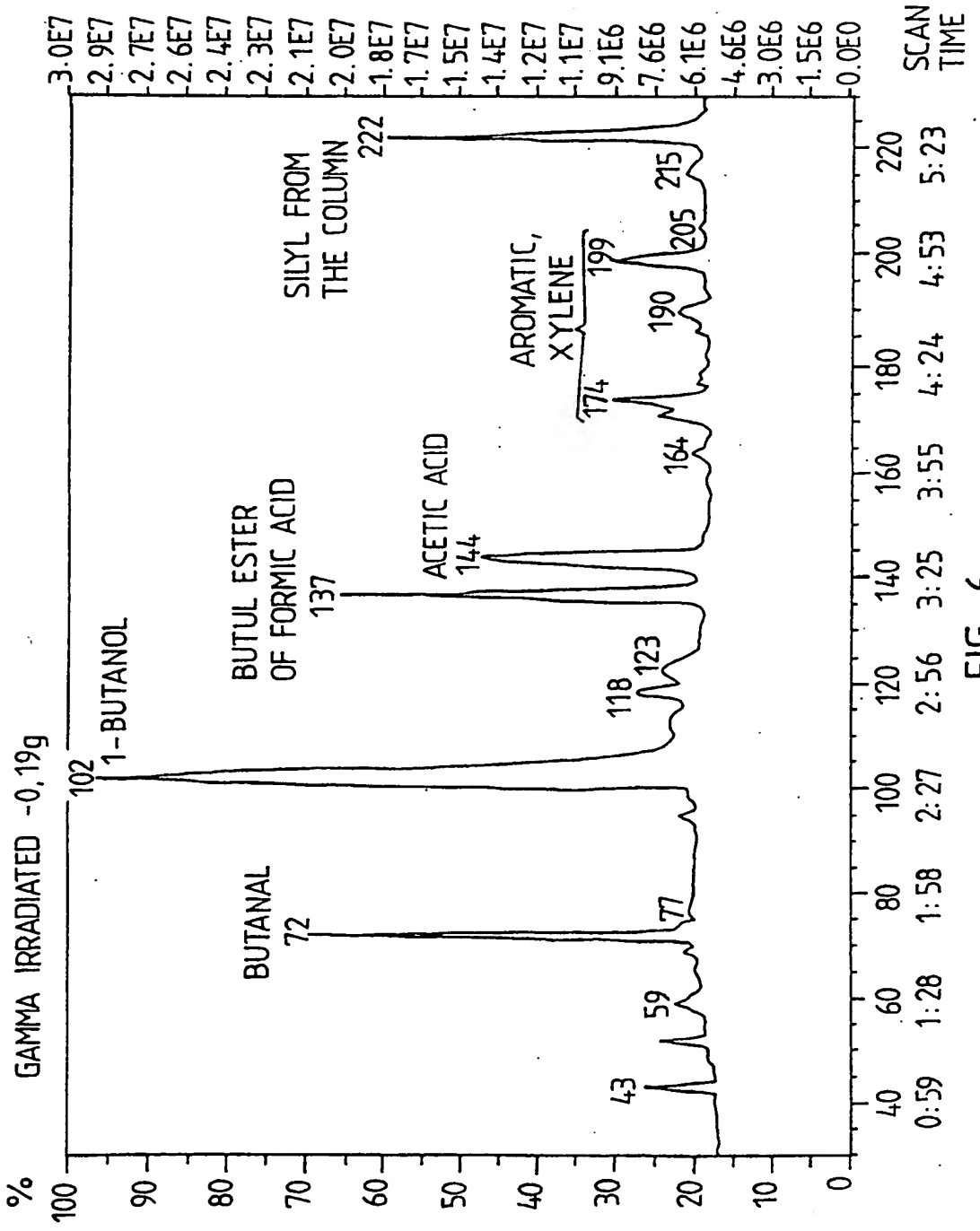
1:58
2:27
2:57
3:26
3:55
4:25
4:54
5:23
40
60
80
100
120
140
160
180
200
220
221
SILYL FROM
THE COLUMN
AROMATIC
197
203
177
168
164
BUTUL ESTER
OF FORMIC ACID
133
138
147
122
128
BUTANOL
98
104
50
70
82

FIG. 5


GAMMA IRRADIATED -0,19g
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80
70
60
50
40
30
20
10
0
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2.9E7
2.7E7
2.6E7
2.4E7
2.3E7
2.1E7
2.0E7
1.8E7
1.7E7
1.5E7
1.4E7
1.2E7
1.1E7
9.1E6
7.6E6
6.1E6
4.6E6
3.0E6
1.5E6
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100
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140
160
180
200
220
BUTANAL
72
1-BUTANOL
102
BUTUL ESTER
OF FORMIC ACID
137
ACETIC ACID
144
SILYL FROM
THE COLUMN
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XYLENE
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59
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118
123
164
174
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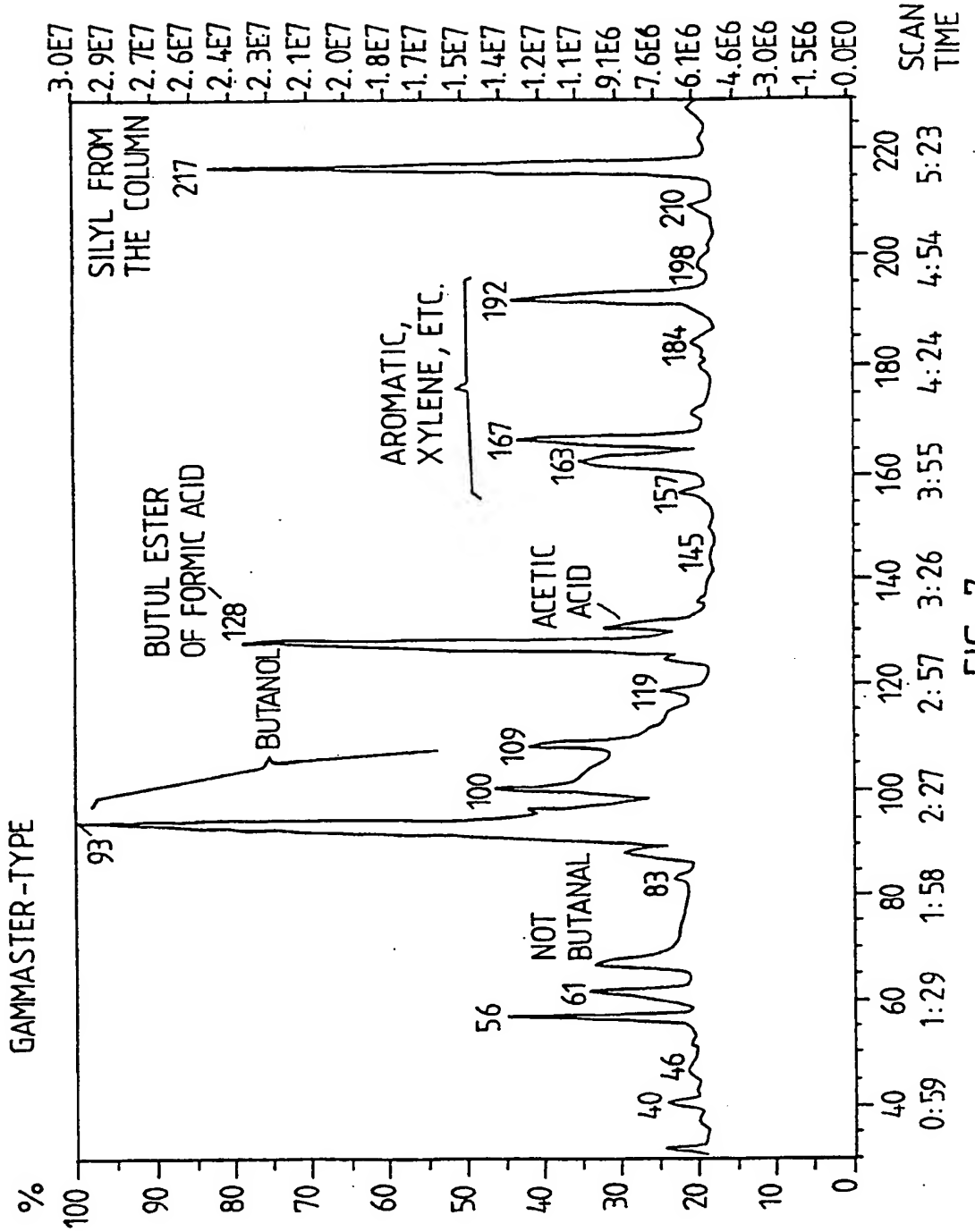
199
205
215

FIG. 6


GAMMASTER-TYPE
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80
70
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40
30
20
10
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3.0E7
2.9E7
2.7E7
2.6E7
2.4E7
2.3E7
2.1E7
2.0E7
1.8E7
1.7E7
1.5E7
1.4E7
1.2E7
1.1E7
9.1E6
7.6E6
6.1E6
4.6E6
3.0E6
1.5E6
0.0E0
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100
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157
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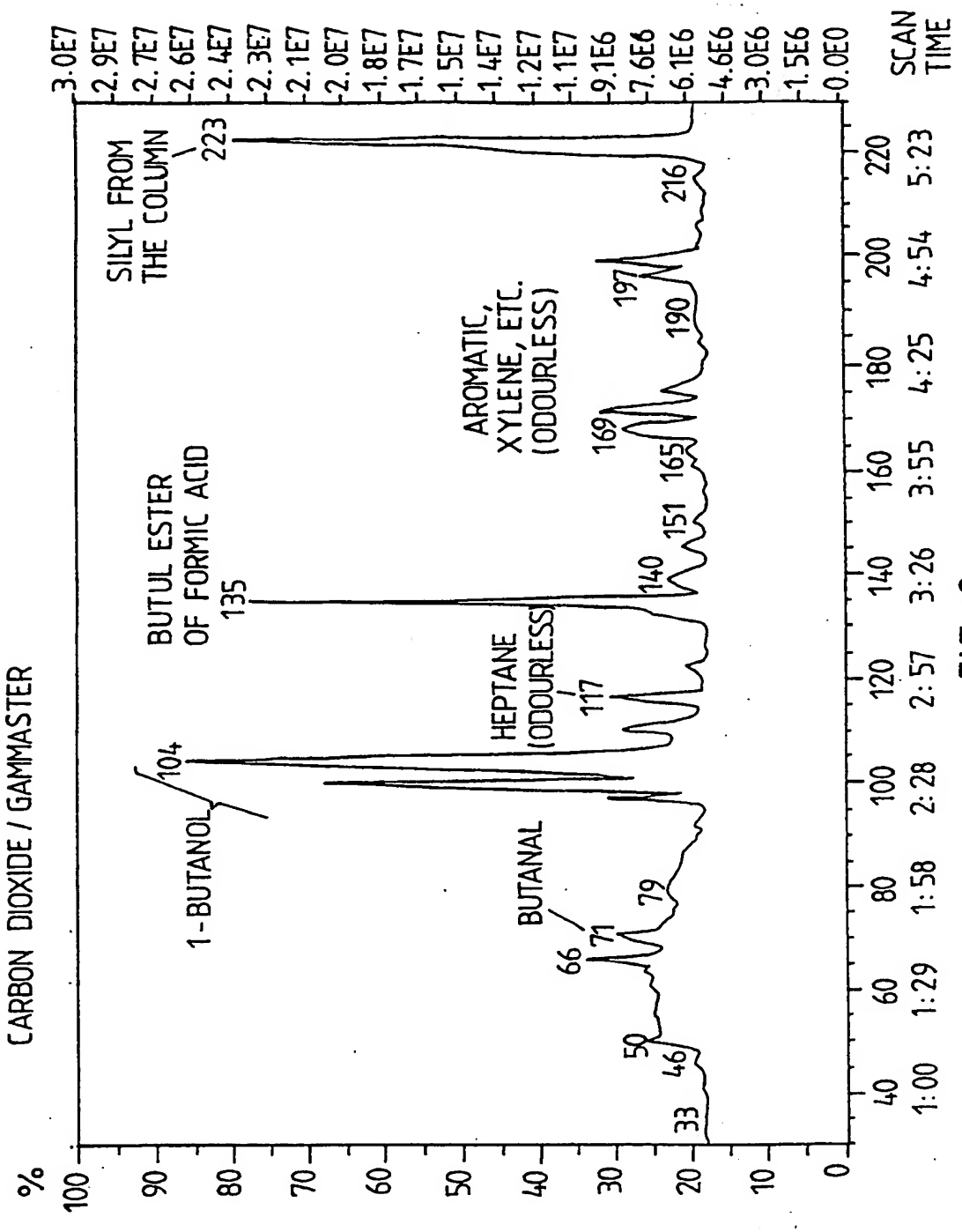
167
184
192
198
210
217
40
46
56
61
83
BUTANOL
BUTUL ESTER
OF FORMIC ACID
ACETIC
ACID
AROMATIC,
XYLENE, ETC.
SILYL FROM
THE COLUMN
NOT
BUTANAL

FIG. 7


CARBON DIOXIDE / GAMMASTER
%
100
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2.7E7
2.6E7
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2.3E7
2.1E7
2.0E7
1.8E7
1.7E7
1.5E7
1.4E7
1.2E7
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9.1E6
7.6E6
6.1E6
4.6E6
3.0E6
1.5E6
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TIME
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2:28
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BUTANAL
66
71
79
50
46
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HEPTANE
(ODOURLESS)
117
BUTUL ESTER
OF FORMIC ACID
135
140
151
165
AROMATIC,
XYLENE, ETC.
(ODOURLESS)
169
190
197
SILYL FROM
THE COLUMN
223
216

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 93/00554

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: B65B 55/02, A61L 2/08
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: B65B, A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5014494 (GEORGE), 14 May 1991 (14.05.91), column 1, line 63 - line 68	1-7
Y	US, A, 4112124 (JARVIS), 5 Sept 1978 (05.09.78), figures 5a-5f	1-7
Y	US, A, 3483005 (W.M. URBAIN; J.L. SHANK; F.L. KAUFFMAN), 9 December 1969 (09.12.69), claim 3	1-7

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"&" document member of the same patent family

Date f the actual completion of the international search	Date of mailing of the international search report
4 March 1994	07 -04- 1994
Name and mailing address f the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Björn Salén Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/01/94

International application No.
PCT/FI 93/00554

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5014494	14/05/91	NONE	
US-A- 4112124	05/09/78	NONE	
US-A- 3483005	09/12/69	NONE	